

Docket No.
4155-102

Declaration For Patent Application

English Language Declaration

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled

**NEW DIAGNOSTIC AND TREATMENT METHODS INVOLVING THE CYSTIC FIBROSIS
TRANSMEMBRANE REGULATOR**

the specification of which

(check one)

☐ is attached hereto.

☒ was filed on JULY 2, 1993 as United States Application No. or PCT International
Application Number 08/087,132
and was amended on DECEMBER 27, 1996

(if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d) or Section 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate or PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Not Claimed

(Number)

(Country)

(Day/Month/Year Filed)

☐

(Number)

(Country)

(Day/Month/Year Filed)

☐

(Number)

(Country)

(Day/Month/Year Filed)

☐

BOARD OF PATENT
APPEALS &
INTERFERENCES
JUN 11 1998

I hereby claim the benefit under 35 U.S.C. Section 119(e) of any United States provisional application(s) listed below:

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

(Application Serial No.)

(Filing Date)

I hereby claim the benefit under 35 U. S. C. Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. Section 112, I acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, CFR Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application:

07/488,307

MARCH 5, 1990

ABANDONED

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

07/259,295

SEPTEMBER 27, 1990

ABANDONED

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

07/613,592

NOVEMBER 15, 1990

ABANDONED

(Application Serial No.)

(Filing Date)

(Status)
(patented, pending, abandoned)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor RICHARD J. GREGORY	
Sole or first inventor's signature <i>Richard J. Gregory</i>	Date 6/4/98
Residence Westford, MA	
Citizenship UNITED STATES	
Post Office Address 2 Wintergreen Lane	
Westford, MA 01886	

Full name of second inventor, if any	
Second inventor's signature	Date
Residence	
Citizenship	
Post Office Address	

Full name of third inventor, if any	
Third inventor's signature	Date
Residence	
Citizenship	
Post Office Address	

Full name of fourth inventor, if any	
Fourth inventor's signature	Date
Residence	
Citizenship	
Post Office Address	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
GREGORY *et al.*

Serial No. 08/087,132

Filed: July 2, 1993

For: NEW DIAGNOSTIC AND
TREATMENT METHODS
INVOLVING THE CYSTIC
FIBROSIS TRANSMEMBRANE
REGULATOR

Group Art Unit: 1814

Examiner: Dr. K.C. Carlson

BOARD OF PATENT
APPEALS &
INTERFERENCES
JUN 11 1998

***DECLARATION OF SENG H. CHENG, ALAN SMITH,
SUCHARITA PAUL, KATHLEEN M. HEHIR, and JOHN MARSHALL***

We, Seng H. Cheng, Alan Smith, Sucharita Paul, Kathleen M. Hehir, and John Marshall, declare that:

1. All statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.
2. This application is a continuation of Serial No. 07/613,592 which is a continuation-in-part of Serial Nos. 07/448,307 and 07/589,295.

3. We understand the subject matter presently claimed in claim 226 of this application is as follows:

-- 226. A recombinant vector comprising a DNA regulatory element operably linked to a DNA molecule that encodes a wild-type, human cystic fibrosis transmembrane conductance regulator protein, wherein the DNA molecule is capable of stable propagation in *E. coli*. --

4. We further understand that the subject matter presently claimed in claim 227 of this application is as follows:

-- 227. A recombinant vector comprising a DNA regulatory element operably linked to a DNA molecule encoding the cystic fibrosis transmembrane conductance regulator protein of Table 1, wherein the DNA molecule is capable of stable propagation in *E. coli* as a result of:

(a) said DNA regulatory element permitting maintenance of the DNA molecule in *E. coli* at a low copy number, or

(b) said nucleotide sequence of the DNA molecule being modified to disrupt its expression in *E. coli* while allowing its expression in mammalian cells. --

5. We understand that claims 226 and 227 are thus limited to recombinant vectors.

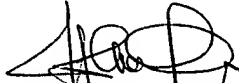
6. We are informed and believe that no other subject matter currently is claimed in this application.

7. As to Sucharita Paul, I, together with Richard J. Gregory and Kathleen M. Hehir, am listed as co-inventor of Serial No. 07/448,307 and, together with Richard J. Gregory, Seng H. Cheng, Alan Smith, Kathleen M. Hehir, and John Marshall, as co-inventor of Serial No. 07/613,592. In 1990, I was a technician at Genzyme Corporation assisting Richard J. Gregory. While I believe I may have contributed to the subject matter of other claims of Serial No. 07/448,307 and Serial No. 07/613,592, I do not believe I am an inventor of the subject matter of claim 226 or the subject matter of claim 227.

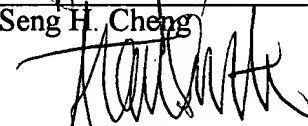
8. As to Kathleen M. Hehir, I, together with Richard J. Gregory and Sucharita Paul, am listed as co-inventor of Serial No. 07/448,307 and, together with Richard J. Gregory, Seng H. Cheng, Alan Smith, Sucharita Paul, and John Marshall, as co-inventor of Serial No. 07/613,592. In 1990, I was involved in DNA sequencing at Genzyme Corporation. While I believe I may have contributed to the subject matter of other claims of Serial No. 07/448,307 and Serial No. 07/613,592, I do not believe I am an inventor of the subject matter of claim 226 or the subject matter of claim 227.
9. As to Seng H. Cheng, I, together with Richard J. Gregory and John Marshall, am listed as co-inventor of Serial No. 07/589,295 and, together with Richard J. Gregory, Alan Smith, Sucharita Paul, Kathleen M. Hehir, and John Marshall, as co-inventor of Serial No. 07/613,592. In 1990, I was involved in antibody work at Genzyme Corporation. While I believe I may have contributed to the subject matter of other claims of Serial No. 07/589,295 and Serial No. 07/613,592, I do not believe I am an inventor of the subject matter of claim 226 or the subject matter of claim 227.
10. As to John Marshall, I, together with Richard J. Gregory and Seng H. Cheng, am listed as co-inventor of Serial No. 07/589,295 and, together with Richard J. Gregory, Seng H. Cheng, Alan Smith, Sucharita Paul, and Kathleen M. Hehir, as co-inventor of Serial No. 07/613,592. In 1990, I was involved in antibody work at Genzyme Corporation. While I believe I may have contributed to the subject matter of other claims of Serial No. 07/589,295 and Serial No. 07/613,592, I do not believe I am an inventor of the subject matter of claim 226 or the subject matter of claim 227.
11. As to Alan Smith, I, together with Richard J. Gregory, Seng H. Cheng, Alan Smith, Sucharita Paul, Kathleen M. Hehir, and John Marshall, am listed as co-inventor of Serial No. 07/613,592. I was Head of Research at Genzyme Corporation in 1990 and the immediate supervisor of Richard J. Gregory. While I believe I may have

contributed to the subject matter of other claims of Serial No. 07/613,592, I do not believe I am an inventor of the subject matter of claim 226 or the subject matter of claim 227.

Date: 5/14/98


Seng H. Cheng

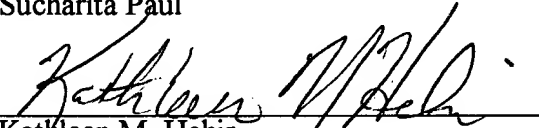
Date: 5/14/98


Alan Smith

Date: _____

Sucharita Paul

Date: 5/14/98


Kathleen M. Hehir

Date: 5/14/98


John Marshall

contributed to the subject matter of other claims of Serial No. 07/613,592, I do not believe I am an inventor of the subject matter of claim 226 or the subject matter of claim 227.

Date: 5/22/98

Sucharita Paul
Sucharita Paul

#55(3)

4155-102US

IG4-9.2FWC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
GREGORY *et al.*

Serial No. 08/087,132

Filed: July 2, 1993

For: NEW DIAGNOSTIC AND
TREATMENT METHODS
INVOLVING THE CYSTIC
FIBROSIS TRANSMEMBRANE
REGULATOR

Group Art Unit: 1814

Examiner: Dr. K.C. Carlson

BOARD OF PATENT
APPEALS &
INTERFERENCES
JUN 11 1998

CONSENT OF ASSIGNEE

Genzyme Corporation, assignee of the entire right, title, and interest in the above application by virtue of an assignment recorded at Reel 6652, Frame 0886, hereby consents to the amendment of inventorship to Richard J. Gregory as sole inventor.

GENZYME CORPORATION

Date: 5/29/98

By:

Elyabeth Laxson

Title:

Director, Genzyme Patenting